

REMARKS

Reconsideration and withdrawal of the Restriction Requirement is respectfully requested in view of the remarks presented herewith.

The November 2, 2005 Office Action required restriction from among the following groups under 35 U.S.C. §121:

- Group I: Claims 1-5, drawn to a non-human animal model of oligodendrocyte developmental disorders, wherein the non-human animal comprises a deficiency in chromosomal DAP12 (DNAX Activation Protein 12) gene function and shows an oligodendrocyte developmental disorder, classified in class 800, subclass 13.
- Group II: Claims 7-13, drawn to an *in vivo* method of screening for a developmental promoter or developmental suppressor of oligodendrocytes, wherein a test substance is administered to the non-human animal model of oligodendrocyte developmental disorders, classified in class 800, subclass 3.
- Group III: Claims 7, 8, 9, 12, drawn to an *in vitro* method of screening for a developmental promoter or developmental suppressor of oligodendrocytes, wherein a test substance is administered to the cell, tissue, or organ of a non-human animal model of oligodendrocyte developmental disorders, classified in class 800, subclass 3.
- Group IV: Claims 14 and 15, drawn to a developmental promoter or a developmental suppressor of oligodendrocytes, classified in class 536, subclass 24.1.
- Group V: Claim 16, drawn to a method of screening for a therapeutic composition for neuropsychiatric disorders using a transgenic non-human animal comprising a deficiency in chromosomal DAP12 gene function, classified in class 800, subclass 3.
- Group VI: Claim 17, drawn to a therapeutic composition for neuropsychiatric disorders obtained by using a transgenic non-human animal

comprising a deficiency in chromosomal DAP12 gene function,
classified in class 514, subclass 1.

Group VII: Claim 18, drawn to a method for diagnosing neuropsychiatric disorders, wherein the symptoms of the non-human animal model comprising a deficiency in chromosomal DAP12 gene function are used to diagnose the neuropsychiatric disorder, classified in class 800, subclass 18.

The Office Action also required election of species relating to neuropsychiatric disorders:

1. Nasu-Hakola disease
2. Dementia
3. schizophrenia
4. schizotypal personality disorders
5. obsessive-compulsive disorders
6. Huntington's disease
7. Tourette's syndrome

Applicants hereby elect, with traverse, the claims of Group I, namely claims 1-5, and Species 2, encompassing dementia as the neuropsychiatric disorder, for further prosecution on the merits.

The MPEP lists two criteria for restriction to be proper. First, the invention must be independent or distinct. MPEP §803. Second, searching the additional invention(s) must constitute an undue burden on the Examiner if restriction is not required. *Id.* The MPEP directs the Examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden...even though it includes claims to distinct or independent inventions.” *Id.*

It is respectfully submitted that as stated in the Office Action, the inventions encompassed by Groups I, II, III, V, and VII fall under the same class, which suggests that it would not be an undue burden on the Examiner to search and examine the claimed subject matter of these Groups. Contrary to the views expressed by the Office, the claims of Groups I, II, III, V, and VII relate to the same inventive concept. Group I, drawn to a non-human animal model, would consequently and inextricably encompass a search of claims included in Groups II and III, which relate to methods of screening for a developmental promoter or developmental suppressor

of oligodendrocytes in the non-human animal of Group I. Groups V and VII also relate to the same inventive concept, as they involve methods of screening therapeutic compositions and diagnosing neuropsychiatric disorders using the non-human animal of Group I. Therefore, a search of the subject matter in the claims of Groups II, III, V, and VII would consequently and inextricably encompass a search of the claims included in Group I. Therefore, it is respectfully submitted that the claims of Groups I, II, III, V, and VII, which relate to a non-human animal and methods of using the product, are subject to rejoinder (MPEP §821.04).

Further, a search of the subject matter of Group IV would also encompass a search of the claims of Groups II and III, because the developmental promoter or developmental suppressor of Group IV is screened by the methods of Groups II and III. Therefore, it is submitted that the claims of Groups II, III, and IV are subject to rejoinder. In addition, Group V, encompassing Claim 16, is drawn to a method of screening for a therapeutic composition. Group VI, encompassing Claim 17, relates to a therapeutic composition for neuropsychiatric disorders, which is screened and obtained by the method described in Group V. Therefore, a search of the subject matter of the claims of Groups V and VI are likely to be co-extensive, and as a result, are also subject to rejoinder.

Regarding the required election of species, Applicants respectfully remind the Examiner that an election of species is only required under M.P.E.P. §808.01(a) “where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention”. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

It is respectfully submitted there is a disclosure of relationship between the claimed species as the species are all types of neuropsychiatric disorders. And, the Office Action has made no showing that searching all of the species of foodstuffs would constitute an undue burden.

In view of the remarks herein, Groups I to VII, as well as species 1-7 comprise a web of knowledge and continuity of effort that merits examination in one application. Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of

GATT, whereby a shortened patent term may result in any divisional applications filed).

Restriction has not been shown to be proper, especially in view of the requisite showing that a serious burden has not been met. Indeed, the search and examination of each Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

In view of the foregoing, reconsideration and withdrawal, or at least, modification of the restriction requirement is respectfully requested.

CONCLUSION

Reconsideration and withdrawal, or modification of the restriction requirement, and a prompt and favorable examination on the merits, is respectfully requested.

Respectfully submitted,
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